Reference number(s)
907-A

Initial Prior Authorization Testosterone – Testopel

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Testopel	testosterone	implant pellets

Indications

FDA-approved Indications

Males

Androgens are indicated for replacement therapy in conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome; or orchiectomy.
- Hypogonadotropic hypogonadism (congenital or acquired) - gonadotropic LHRH deficiency, or pituitary - hypothalamic injury from tumors, trauma or radiation.

If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sex characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

Safety and efficacy of Testopel (testosterone pellets) in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established.

- Androgens may be used to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary

to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the patient and parents prior to androgen administration. An x-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

Coverage Criteria

Delayed Puberty

Authorization may be granted when the requested drug is being prescribed for delayed puberty when the following criteria is met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
- Before the start of testosterone therapy, the patient has at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values.

Continuation of Therapy

Delayed Puberty

All patients (including new patients) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

Primary or Hypogonadotropic Hypogonadism

Authorization may be granted when the requested drug is being prescribed for primary or hypogonadotropic hypogonadism when ALL of the following criteria are met:

- The requested drug is NOT being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism). [NOTE: Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.]
- Before the patient started testosterone therapy, the patient had a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values.

Duration of Approval (DOA)

- 907-A: DOA: 12 months

References

1. Testopel (testosterone pellets) [package insert]. Malvern, PA: Endo USA; March 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 4, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/. (cited: 02/04/2025).
4. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone Therapy in Men with Hypogonadism: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2018;103(5):1715-1744.

Document History

Written by: UM Development (MG)

Date: 05/2003

Revised: (NB) 01/2005; (MG) 02/2006; (NB) 02/2007(2); (AM) 01/2008, 12/2008; (MS) 11/2009, 11/2010; (TM) 11/2011, 10/2012 (extended duration); (PL) 11/2012, 11/2013 (changed to Testopel MDC-1); (CF/JH) 11/2014, 02/2015 (updated testosterone level question), 11/2015, 11/2016; (KC) 11/2017 (no clinical changes), 10/2018 (no clinical changes), 08/2019 (removed "male" from lab questions), 10/2019 (removed MDC from title), 02/2020 (no clinical changes), 02/2021 (added age-related hypogonadism question); (VLS) 02/2022 (no clinical changes); (MRS) 02/2023 (no clinical changes), 02/2024 (no clinical changes); (DMH) 02/2025 (no clinical changes)

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Reviewed: CDPR/Medical Affairs (MM): 01/2005, 02/2006; (WF): 02/2007, 01/2008, 12/2008, 11/2009; (KP) 11/2010, 11/2011, 03/2012, 10/2012; (DNC) 11/2012; (LCB) 11/2013; (SES) 11/2014; (KRU) 02/2015; (LCB) 11/2015; (MC) 12/2016; (SD) 02/2017; (EPA) 08/2019; (CHART) 10/31/19, 02/27/20, 02/25/21, 02/24/2022, 03/02/2023, 02/29/2024, 02/27/2025

External Review: 08/2005, 04/2006, 06/2007, 04/2008, 04/2009, 02/2010, 02/2011, 03/2012, 02/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019, 10/2019 (FYI), 02/2020, 06/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for age-related hypogonadism (also referred to as late-onset hypogonadism)? [Safety and efficacy of testosterone products in patients with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established.] [If Yes, then no further questions. If No, then go to 2.]	Yes	No
2	Is the requested drug being prescribed for primary or hypogonadotropic hypogonadism? [If Yes, then go to 3. If No, then go to 6.]	Yes	No
3	Is this request for continuation of therapy? [If Yes, then go to 4. If No, then go to 5.]	Yes	No
4	Before the patient started testosterone therapy, did the patient have a confirmed low morning testosterone level according to current practice guidelines or your standard lab reference values? [No further questions]	Yes	No
5	Does the patient have at least TWO confirmed low morning testosterone levels according to current practice guidelines or your standard lab reference values, before the start of testosterone therapy? [No further questions]	Yes	No
6	Is the requested drug being prescribed for delayed puberty? [No further questions]	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Deny	Go to 2	We have denied your request because your plan does not cover this drug for age-related hypogonadism, also referred to as late-

			onset hypogonadism. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Exclusion, age-related hypogonadism]
2.	Go to 3	Go to 6	
3.	Go to 4	Go to 5	
4.	Approve, 12 Months	Deny	Your plan only covers this drug when you had a morning testosterone test before you started testosterone treatment and your test results were in a certain range (low). We denied your request because: A) You did not have a morning testosterone test before you started treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Continuation, lab/test]
5.	Approve, 12 Months	Deny	Your plan only covers this drug when you have had two morning testosterone tests before starting treatment and your test results are in a certain range (low). We denied your request because: A) You did not have two morning testosterone tests before starting treatment, or B) Your results were not in the approvable range. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Lab/test]

6.	Approve, 12 Months	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are primary hypogonadism, hypogonadotropic hypogonadism, and delayed puberty. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis]